Local Health Department Food Protection Program Survey Data Collection

The new survey instrument will be used to gather data as part of the Indiana State Department of Health (ISDH) Food Protection Program's self assessment using the FDA National Voluntary Retail Food Protection Program Standards and the Healthy People 2010's 10 Essential Public Health Services.

This survey tool was developed based on survey tools used by the Program in the past and on the new aforementioned standards and essential services. Part 1 of the survey is to collect census data, which the ISDH has traditionally done every 10 years, on numbers and types of facilities. You will note that we have two types of groupings of classifications. These answers will be subjective based on determinations made by the local program, but can be very useful. The facilities by menu type are found in the back of the ISDH Rule 410 IAC 7-24, Appendix A, and should currently be collected on inspection reports. The second part relates to staffing resources and how many full time equivalents (FTE) are dedicated to the food protection program activities in each department. The 3rd section of Part 1 relates to electronic systems that may be used for food establishment data and whether or not systems and equipment have been provided.

Part 2 of the survey follows the 9 FDA Standards and asks very brief summary questions that relate to the appropriate standard. The applicable Essential Service is also designated in each subsection. The following is an introduction and explanation of the purpose of the standards. The intent is for the local jurisdictions to become much more familiar with the standards and make strides toward improving their programs by attempting to meet the standards. Currently there is no audit process, however, FDA does plan to develop an auditing system for the self assessment process.

INTRODUCTION

Achieving national uniformity among regulatory programs responsible for retail food protection in the United States has long been a subject of debate among the industry, regulators and consumers. Adoption of the FDA Food Code at the state, local and tribal level has been a keystone in the effort to promote greater uniformity. However, a missing piece has been a set of widely recognized standards for regulatory programs that administer the Food Code. To meet this need FDA has developed the Voluntary National Retail Food Regulatory Program Standards (Program Standards) through ideas and input from federal, state, and local regulatory officials, industry, trade and professional associations, academia and consumers on what constitutes a highly effective and responsive retail food regulatory program.

In March of 1996, the FDA hosted a meeting to explore ways in which its retail food protection program could be improved. Participants in the meeting included FDA Retail Food Specialists, FDA headquarters personnel, state and local regulatory officials from the six FDA regions, the president of the Association of Food & Drug Officials, and industry representatives. Following that meeting, FDA established a National Retail Food Team comprised of the Regional Retail Food Specialists, CFSAN personnel and other FDA personnel directly involved in retail food protection. A Retail Food Program Steering Committee

was established and tasked with leading the team to respond to the direction given by the participants in the meeting, i.e. providing national leadership, being equal partners, being responsive, and providing communication and promoting uniformity.

The Steering Committee was charged with developing a five-year operational plan for FDA's retail food program. The Steering Committee was also charged with ensuring the operational plan was in keeping with the goals and mission of the President's Food Safety Initiative. FDA solicited input from the regulatory community, industry and consumers in developing the plan. The resulting Operational Plan charted the future of the National Retail Food Program and prompted a reassessment of the respective roles of all stakeholders and how best to achieve program uniformity.

From the goals established in the Operational Plan, two basic principles emerged on which to build a new foundation for the retail program:

- Promote active managerial control of the risk factors most commonly associated with foodborne illness in food establishments, and
- Establish a recommended framework for retail food regulatory programs within which the active managerial control of the risk factors can best be realized.

These principles led to the drafting of standards that encourage voluntary participation by the regulatory agencies at the state, local, and tribal level. The Program Standards were developed with input obtained through a series of meetings over a two-year period including: the 1996 stakeholders meeting, FDA Regional Seminars, meetings with state officials hosted by the Retail Food Specialists, and six Grassroots Meetings held around the country in 1997. Valuable input from industry associations, associations of regulatory officials, and others was also obtained. The Program Standards were provided to the Conference for Food Protection for further input and to achieve broad consensus among all stakeholders.

In developing the Program Standards, FDA recognized that the ultimate goal of all retail food regulatory programs is to reduce or eliminate the occurrence of illnesses and deaths from food produced at the retail level and that there are different approaches toward achieving that goal. Federal, state, local, and tribal agencies continue to employ a variety of mechanisms with differing levels of sophistication in their attempt to ensure food safety at retail.

While the Program Standards represent the food safety program to which we ultimately aspire, they begin by providing a foundation upon which all regulatory programs can build through a continuous improvement process. The Standards encourage regulatory agencies to improve and build upon existing programs. Further, the Standards provide a framework designed to accommodate both traditional and emerging approaches to food safety. The Program Standards are intended to reinforce proper sanitation (good retail practices) and operational and environmental prerequisite programs while encouraging regulatory agencies and industry to focus on the factors that cause and contribute to foodborne illness.

PURPOSE

The Program Standards serve as a guide to regulatory retail food program managers in the design and management of a retail food regulatory program and provide a means of recognition for those programs that meet these standards. Program manager and administrators may establish additional requirements to meet individual program needs.

The Program Standards are designed to help food regulatory programs enhance the services they provide to the public. When applied in the intended manner, the Program Standards should:

- Identify program areas where an agency can have the greatest impact on retail food safety
- Promote wider application of effective risk-factor intervention strategies
- Assist in identifying program areas most in need of additional attention
- Provide information needed to justify maintenance or increase in program budgets
- Lead to innovations in program implementation and administration
- Improve industry and consumer confidence in food protection programs by enhancing uniformity within and between regulatory agencies

Each standard has one or more corresponding appendices that contain forms and worksheets that facilitate the collection of information needed to fully assess a retail program. Regulatory agencies may use existing, available records or may choose to develop and use alternate forms and worksheets that capture the same information. The complete set of documents can be found at http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm124968.htm

SCOPE

The Program Standards apply to the operation and management of a retail food regulatory program that are focused on the reduction of risk factors known to cause or contribute to foodborne illness and to the promotion of active managerial control of these risk factors. The results of a self-assessment against the Standards may be used to evaluate the effectiveness of food safety interventions implemented within a jurisdiction. The Standards also provide a procedure for establishing a database on the occurrence of risk factors that may be used to track the results of regulatory and industry efforts over time.

NEW DEVELOPMENTS

The Program Standards were pilot tested in each of the five FDA regions in 1999. Each regulatory participant reported the results at the 2000 Conference for Food Protection. Improvements to the Standards were incorporated into the January 2001 version based on input from the pilot participants. Further refinements to the Standards were made in subsequent drafts leading up to the endorsement of the March 2002 version of the Program Standards by the 2002 Conference for Food Protection. The April 2003 version contains enhancements to the forms and worksheets in the Appendices to improve their usefulness. The January 2005 version contains revisions to Standard 1, 5, and 9 based on recommendations approved at the 2004 Conference for Food Protection.

In maintaining these standards, FDA intends to allow for and encourage new and innovative approaches to the reduction of factors that are known to cause foodborne illness. Program managers and other health professionals participating in this voluntary program who have demonstrated means or methods other than those described here may submit those to FDA for consideration and inclusion in the

Program Standards. Improvements to future versions of the Standards will be made through a process that includes the Conference for Food Protection to allow for constant program enhancement and promotion of national uniformity.

IMPACT ON PROGRAM RESOURCES

During pilot testing of the Program Standards in 1998, some jurisdictions reported that the self-assessment process was time consuming and could significantly impact an agency's resources. Collection, analysis, and management of information for the database were of special concern. However, participating jurisdictions also indicated that the resource commitment was worthwhile and that the results of the self-assessment were expected to benefit their retail food protection program. Advance planning is recommended before beginning the data collection process in order to use resources efficiently. It is further recommended that jurisdictions not attempt to make program enhancements during the self-assessment process. A better approach is to use the self-assessment to identify program needs and then establish program priorities and plans to address those needs as resources become available.

Standard 1 - Regulatory Foundation and Essential Service # 6 - Enforce Laws

This standard applies to the regulatory foundation used by a retail food program. Regulatory foundation includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment.

Requirement Summary

The regulatory foundation includes provisions for:

1. The public health interventions contained in the *Food Code;*
2. Control measures for the risk factors known to contribute to foodborne illness;
3. Good Retail Practices (GRP's) at least as stringent as the *Food Code*; and
4. Compliance and enforcement at least as stringent as the selected provisions from *Food Code* and Annex 1 of the *Food Code*.

Description of Requirement

1. **Food Code Interventions and Risk Factor Control Measures**

   The regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the *Food Code*. To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed in Appendix A, Table A-1 and summarized in Table A-2, from #1 'Demonstration of Knowledge' through #11 'Highly Susceptible Populations'. For initial listing, the regulatory foundation must contain at least 9 of the 11 interventions and risk factor controls. In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third audit.

2. **Good Retail Practices**

   The regulations contain provisions that address Good Retail Practices that are at least as stringent as those described in the *Food Code*. To meet this element of the Standard, regulations must have a corresponding requirement for 95 percent of the *Food Code* sections as listed in Appendix A, Table A-3 and summarized in Table A-4, from #12 'Personnel' through #37 'Variance for Smoking'.

3. **Compliance and Enforcement**

   The regulations contain provisions that address Compliance and Enforcement requirements that are at least as stringent as those contained in the *Food Code*. To meet this element of the Standard, regulations must have a corresponding requirement for each of the *Food Code* sections as listed in Appendix A, Table A-5, items 1 through 11. For item 12 pertaining to 'Legal Remedies', a corresponding regulatory requirement must be in place for at least one of the sections pertaining to criminal, injunctive, or civil penalties.

Outcome

The desired outcome of this standard is the adoption of a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry.

Documentation

The quality records needed for this standard include:

1. The County Food Ordinance that has adopted the correct statutes and rules that govern the operation of a food establishments under their jurisdiction.

Standard 2 - Trained Regulatory Staff and Essential Service #8 – Assure a Competent Workforce

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

Step 1 - Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting any independent routine inspections.

Step 2 - Completion of a minimum of 25 joint field training inspections and successful completion of the jurisdiction's FSIO Assessment of Field Training Manual similar to the process developed by the Conference for Food Protection. The Field Training Manual and Forms can be accessed from the CFP web site at http://www.foodprotect.org/.

Step 3 - Completion of a minimum of 25 independent inspections and remaining course curriculum (designated as "post" courses) outlined in Appendix B-1.

Step 4 - Completion of a standardization process similar to the FDA standardization procedures.↓

Step 5 - Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 18 months of hire or assignment to the retail food protection program.
- Step 5 every 36 months after the initial 18 months of training.

Step 1 - Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills

There are two options for demonstrating successful completion of these pre-requisite ("Pre) courses.

OPTION 1:

Successful completion of the FDA ORA U pre-requisite courses/exercises/examinations identified as "Pre" in Appendix B-1

AND

training on the jurisdiction's prevailing statutes; regulations and/or ordinances.

NOTE: The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.

OPTION 2:

Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U pre-requisite ("Pre") courses,

AND

training on the jurisdiction's prevailing statutes, regulations and/or ordinances,

AND

successful passing of one of the four written examination options (described later in this Standard) for determining whether a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link.

Note: While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:

- Logs/records that are completed based on sign-in sheets; or
- Information validated from the certificate at the time-of-issuance; or
- A college transcript with a passing grade or other indication of successful completion of the course; or
- Automated attendance records, such as those currently kept by some professional associations and state agencies, or
- Other accurate verification of actual attendance.

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORA U courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or
2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or

3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or
4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: Within the context of this Standard, the written examinations are part of a training process; **NOT** a standardization/certification process. The examinations listed are **NOT** to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.

Step 2 - Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer or the jurisdiction's designated staff member, who has successfully completed all training elements required by this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

Demonstration inspections are those in which the jurisdiction's trainer and/or designated staff person takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

As part of the 25 joint field inspections, the jurisdiction's trainer will conduct an Assessment of Training Needs (ATN and will soon be referred to as the Training Manual) on those joint inspections performed as "training" inspections where the candidate takes the lead using a process and forms similar to the ones presented in The Guide to Conducting ATN. The ATN is designed not only to assess a Food Safety Inspection Officer's readiness to conduct independent inspections, but also to provide valuable feedback on the jurisdiction's food safety training process.

Note: The ATN provides structure to the FSIO performance assessment. The performance assessment is part of a training process that provides both candidate and assessor feedback on specific knowledge, skills and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.

- The ATN is **NOT** intended to be used for certification or licensure purposes.
- Regulatory jurisdictions are **NOT** to use the ATN for administrative purposes including but not limited to, job classifications, promotions, or disciplinary actions up to and including termination.

FSIOs must successfully complete the ATN prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2005 FDA Food Code) need to provide web site for this info. The jurisdiction's trainer/food program manager can make a determination as to the FSIO's readiness to conduct independent inspections of risk category 1 establishments as defined in Appendix B-3 at any time during the training process.

note: The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement. In lieu of the 25 joint field inspections, an ATN of experienced FSIOs must be conducted to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.

Step 3 - Independent Inspections and Completion of ALL Curriculum Elements

Within 18 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following six curricula areas, must be completed within this 18 month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology; and
6. HACCP.

All courses for each of the curriculum areas must be successfully completed within 18 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

note: The estimated contact time for completion of the FDA ORA U "post" courses is 16 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses/exercises/exams listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses. A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA web site.

Step 4 – Food Safety Inspection Officer – Field Standardization

Within 18 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the 'FDA Standardization Procedures.' The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

Note: The field standardization criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol **must** include the five performance areas outlined above in Step 4.

It should be noted that it is possible and highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspection. However to meet Standard #2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors, and communicates vital information about the inspection in a way that can be received, understood and acted upon by management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard #2 criteria within the 18 month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5 – Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (18 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local); and
4. Food safety related conferences and workshops;
5. Distance learning opportunities that pertain to food safety, such as:
    - WEB based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
    - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

6. Presentations at professional conferences;
7. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety;
8. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period.

note: Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.

A maximum of four (4) contact hours may be accrued for:

9. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted,
- transcripts from a college or university; or
- a letter from the administrator of the continuing education program attended.
- a copy of the peer-reviewed article or presentation made at a professional conference.
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

note: The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, keeps

the records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);
2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process based on an Assessment of Training Needs;
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

Standard 3 - Inspection Program Based on HACCP Principles - Essential Service #1 – Monitor and #6 - Enforce Laws

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

Requirement Summary

An inspection program that focuses on the status of risk factors, determines and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

1. Implements the use of an inspection form that is designed for:
    1. The identification of risk factors and interventions.

    2. Documentation of the compliance status of each risk factor and intervention (i.e. a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
    3. Documentation of all compliance and enforcement activities and
    4. Requires the selection of IN, OUT, NO, or NA for each risk factor.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk.
4. Develops and implements a program policy that requires:
    1. On-site corrective actions* as appropriate to the type of violation.
    2. Discussion of long-term control** of risk factor options, and
    3. Follow-up activities.
5. Establishes and implements written polices addressing code variance requests related to risk factors and interventions.
6. Establishes written policies regarding the verification and validation of HACCP plans when a plan is required by the code.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:

1. Inspection form that requires the selection of IN, OUT, NO, or NA, (not developed in IN yet)
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category,
3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections.

***Note: On-site** corrective action as appropriate to the violation would include such things as:

1. Destruction of foods that have experienced extreme temperature abuse,
2. Embargo or destruction of foods from unapproved sources,
3. Accelerated cooling of foods when cooling time limits can still be met,
4. Reheating when small deviations from hot holding have occurred,
5. Continued cooking when proper cooking temperatures have not been met.
6. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
7. Required hand washing when potential contamination is observed.

Note: Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

Standard 4 - Uniform Inspection Program; Essential Service #6 – Enforce Laws

This standard applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance / enforcement procedures.

Requirement Summary

Program management has established a quality assurance program to ensure uniformity among regulatory staff in the interpretation and application of laws, regulations, policies, and procedures.

Description of Requirement

1. Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff. The quality assurance program shall:
    A. Be an on-going program.
    B. Assure that each inspector:
        1. Determines and documents the compliance status of each risk factor and intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable is noted on the inspection form) through observation and investigation;
        2. Completes an inspection report that is clear, legible, concise, and accurately records findings, observations and discussions with establishment management;
        3. Interprets and applies laws, regulations, policies and procedures correctly;
        4. Cites the proper local code provisions for CDC-identified risk factors and Food Code interventions;
        5. Reviews past inspection findings and acts on repeated or unresolved violations;
        6. Follows through with compliance and enforcement;
        7. Obtains and documents on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation;
        8. Documents the options for the long-term control of risk factors were discussed with establishment managers when the same out-of control risk factor occurred on consecutive inspections. Options may include but are not limited to risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans;

9. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met; and
10. Files reports and other documentation in a timely manner.

C. Describe the actions that will be implemented when the program analysis identifies deficiencies in quality or consistency in any program aspect listed in 1) B.

2. The quality assurance program must achieve an overall inspection program performance rating for each of the ten measured aspects [Items1-10] of at least 75% using the following self-assessment procedure and the appropriate Table in Supplement to Standard 4 (Appendix D).

   An assessment review of each inspector's work shall be made during at least two joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports of the same inspected establishments, during every self-assessment period.

Outcome

A quality assurance program exists that ensures uniform, high quality inspections.

Documentation

The quality records needed for this standard include:

1. A written procedure that describes the jurisdiction's quality assurance program that meets the criteria under Description of Requirement section 1) B., including corrective actions for deficiencies, and
2. Documentation that the program achieves a 75 percent performance rating on each aspect using the self-assessment procedures described above and in Supplement to Standard 4 (Appendix D).

Standard 5 - Foodborne Illness and Food Defense Preparedness and Response; Essential Service #2 – Diagnose and Prevent

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate that result in illness, injury and outbreaks.

Requirement Summary

The program has an established system to detect, collect, investigate and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

Description of Requirement

1. **Investigative Procedures**
    a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and injury. The procedures clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.
    b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, injury or contamination of food.
    c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties and responsibilities of each party.
    d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, injury or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.
    e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.
    f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.
    g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site illness, injury, or outbreak investigations
    h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.
    i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.
2. **Reporting Procedures**
    a. Possible contributing factors to the illness, injury or intentional food contamination are identified in each on-site investigation report.
    b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed outbreaks with CDC.
3. **Laboratory Support Documentation**
    a. The program has a letter of understanding, written procedures, contract or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.
    b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).
4. **Trace-back Procedures**

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. **Recalls**
    a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.
    b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.
    c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.
6. **Media Management**
    a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.
7. **Trend Analysis**
    a. At least once per year, the program conducts a review of the data in the complaint log or database and the illness and injury investigations to identify trends and possible contributing factors that are most likely to cause illness or injury. These periodic reviews of multiple complaints and contributing factors may suggest a need for further investigations and may suggest steps for illness prevention.
    b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:
        1. 1) Multiple complaints on the same establishment;
        2. 2) Multiple complaints on the same establishment type;
        3. 3) Multiple complaints implicating the same food;
        4. 4) Multiple complaints associated with similar food preparation processes;
        5. 5) Number of laboratory-confirmed, food-related outbreaks;
        6. 6) Number of non-laboratory-confirmed but epidemiologically linked, food-related outbreaks;
        7. 7) Contributing factors most often identified;
        8. 8) Number of complaints involving real and alleged threats of intentional food contamination; and
        9. 9) Multiple complaints involving the same agent and any complaints involving unusual agents.
    c. In the event that there have been no illness or injury outbreak investigations conducted during the twelve months prior to the trend analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual illness outbreak and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no illness outbreak investigations occur.

Outcome

A food regulatory program has a systematic approach for the detection, investigation, response, documentation and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination.

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food related illness, injury complaints maintained and current.
2. Collection forms specified in the operating procedures
3. Investigation reports of alleged food related illness, injury, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts or MOU's with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual trend analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

Standard 6 - Compliance and Enforcement; Essential Service #6 - Enforce Laws

This standard applies to all compliance and enforcement activities used by a jurisdiction to achieve compliance with regulations.

Requirement Summary

Compliance and enforcement activities result in follow-up actions for out-of-control risk factors and timely correction of code violations

Description of Requirement

Compliance and enforcement encompasses all voluntary and regulatory actions taken to achieve compliance with regulations. Voluntary corrective action includes, but is not limited to, such activities as on-site corrections at time of inspection, voluntary destruction of product, risk control plans and remedial training. Enforcement action includes, but is not limited to, such activities as warning letters, re-inspection, citations, administrative fines, permit suspension and hearings. Compliance and enforcement options may vary depending on state and local law.

The program must demonstrate credible follow-up for each violation noted during an inspection, with particular emphasis being placed on risk factors that most often contribute to foodborne illness and *Food Code* interventions intended to prevent foodborne illness. The resolution of out-of-compliance risk factors and/or *Food Code* interventions must be documented in each establishment record. The essential program elements required to meet this standard are:

1. A written step-by-step procedure that describes how compliance and enforcement tools are to be used to achieve compliance.
2. Inspection report form(s) that record and quantify the compliance status of risk factors and interventions and (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
3. Documentation on the establishment inspection report form or in the establishment file that compliance and/or enforcement action was taken to achieve compliance at least 80 percent of the time when out-of-control risk factors or interventions are recorded on a routine inspection measured using the procedures in Supplement to Standard 6, Appendix F.
4. Compliance and enforcement actions that follow the step-by-step procedure.

Outcome

The desired outcome of this standard is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

Documentation

The quality records needed for this standard include:

1. A copy of the written step-by-step enforcement procedures.
2. Inspection form that meets the criteria.
3. Documentation that compliance and enforcement action was taken 80 percent of the time using the worksheet and procedures in Supplement to Standard 6, Appendix F, when out-of-control risk factors or code interventions are recorded on routine inspections.
4. A reference "Key" which identifies the major risk factors and *Food Code* interventions on the jurisdiction's inspection report form. [Note: A jurisdiction will not be penalized under Standard No. 6 for sections of the *Food Code* which have not yet been adopted].

Standard 7 - Industry and Community Relations; Essential Service #3 – Inform and Educate

This standard applies to industry and community outreach activities utilized by a regulatory program to solicit a broad spectrum input into a comprehensive regulatory food program, communicate sound public health food safety principles, and foster and recognize community initiatives focused on the reduction of foodborne disease risk factors.

Requirement Summary

The jurisdiction documents participation in forums that foster communication and information exchange among the regulators, industry and consumer representatives.

The jurisdiction documents outreach activities that provide educational information on food safety.

Description of Requirement

1. **Industry and Consumer Interaction**

   The jurisdiction sponsors or actively participates in meetings such as food safety task forces, advisory boards or advisory committees. These forums shall present information on food safety, food safety strategies and interventions to control risk factors. Offers of participation must be extended to industry and consumer representatives.

2. **Educational Outreach**

   Outreach encompasses industry and consumer groups as well as media and elected officials. Outreach efforts may include industry recognition programs, web sites, newsletters, FightBAC™ campaigns, food safety month activities, food worker training, school-based activities, customer surveys or other activities that increase awareness of the risk factors and control methods to prevent foodborne illness. Outreach activities may also include posting inspection information on a web site or in the press.

Agency participation in at least one activity in each of the above categories annually is sufficient to meet this standard.

Outcome

The desired outcome of this standard is enhanced communication with industry and consumers through forums designed to solicit input to improve the food safety program. A further outcome is the reduction of risk factors through educational outreach and cooperative efforts with stakeholders.

Documentation

Quality records needed for this standard reflect activities over the most recent three-year period and include:

1. Minutes, agendas or other records that forums were conducted,
2. For formal, recurring meetings, such documents as by-laws, charters, membership criteria and lists, frequency of meetings, roles, etc.,
3. Documentation of performed actions or activities designed with input from industry and consumers to improve the control of risk factors, or
4. Documentation of food safety educational efforts.

Statements of policies and procedures may suffice if activities are continuous, and documenting multiple incidents would be cumbersome, i.e., recognition provided to establishments with exemplary records or an on-going web site.

Standard 8 - Program Support and Resources; Essential Service #8 – Assure a Competent Workforce

This standard applies to the program resources (budget, staff, equipment, etc.) necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors known to contribute to foodborne illness.

Requirement Summary

The program provides funding, staff and equipment necessary to accomplish compliance with the Voluntary National Retail Food Regulatory Program Standards.

Description of Requirement

The program budget provides the necessary resources to develop and maintain a retail food safety program that meets the following criteria:

1. **Staffing Level**

   A staffing level of one full-time equivalent (FTE) devoted to food for every 280 - 320 inspections performed*. Inspections for purposes of this calculation include routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews and other direct establishment contact time such as on-site training.

   A process should exist for the regulated food establishments to be grouped into at least three categories based on food safety risk (See Standard 3). The number of inspections assigned per FTE should be adjusted within the 280-320 range depending upon the composition of low- to high-risk establishments in the assigned inventory. When an FTE is divided between program areas, the total number of food inspections planned for that FTE should be adjusted to compensate for the additional training time required to maintain competency in multiple program areas. An adjustment of planned inspections per FTE should also occur when food establishments are geographically dispersed due to increased travel time.

2. **Inspection Equipment**

   Inspection equipment of each inspector to include head covers, thermocouples, flashlights, sanitization test kits, heat sensitive tapes or maximum registering thermometers, necessary forms and administrative materials. The following equipment must be available for use by inspectors when needed: computers, cameras, black lights, light meters, pH meters, foodborne illness investigation kits, sample collection kits, data loggers and cell phones.

3. **Administrative Program Support**

   Equipment for administrative staff to include computers, software and/or items necessary to support the record keeping system utilized by the program. A system is in place to collect, analyze, retain and report pertinent information.

4. **Trained Regulatory Staff**

   Training and training documentation for all regulatory staff to meet the level specified in Standard No. 2.

5. **Insspection Program Based on HACCP Principles**

   Staff to meet all of the requirements in Standard No. 3, inspection based on HACCP principles.

6. **Uniform Inspection Program**

   Administrative and supervisory staff to administer and monitor a uniform inspection program based on HACCP principles that meet Standards No. 3 and 4.

7. **Foodborne Illness and Food Defense Preparedness & Response**

   Staff and resources to maintain a foodborne illness investigation and response system that meets Standard No. 5.

8. **Compliance & Enforcement**

   A program that demonstrates follow-through on all compliance and enforcement actions initiated according to the written step-by-step procedures required in Standard No. 6.

9. **Industry & Community Relations**

   An industry and consumer relations program as specified in Standard No. 7.

10. **Program Assessment**

    Sufficient staff and resources to conduct regular program self-assessment and risk factor surveys as specified in Standard No. 9.

11. **Accredited Laboratory**

    Funds to provide access to accredited laboratory resources in support of the program as specified under these nine Standards.

The essential program elements required to demonstrate compliance with this standard are:

A. Full-time equivalent (FTE) personnel to inspections accomplished ratio as described in section 1.
B. Inspection equipment assigned or available as described in section 2.
C. Equipment and/or supplies required for administering the program as described in section 3.
D. A full and accurate completion of Appendix H for Standards 1-7 and Standard 9 whether or not those standards are met.

Outcome

The desired outcome of this standard is that resources are available to support a risk-based retail food safety program designed to reduce the risk factors known to contribute to foodborne illness.

Documentation

The quality records needed for this standard include:

1. Documentation of FTE to inspections ratio,
2. Inventory of assigned and available inspection equipment,
3. Documentation and demonstration of records system and adequacy of support.
4. The completed Appendix H

*NOTE: An average workload figure of 150 establishments per FTE with two inspections per year was originally recommended in the 1976 Food Service Sanitation Manual, the standard originating from a book entitled, "Administration of Community Health Services." Annex 4 of the Code since 1993 has included a recommendation that 8 to 10 hours be allocated for each establishment per year to include all the activities reflected here in the definition of an inspection. The range of 280 – 320 broadly defined inspections per FTE is consistent with these previous recommendations. A measure of resources defined as inspections per FTE rather than establishments per FTE allows for the same unit of measure to be used for any jurisdiction regardless of the frequency of routine inspections conducted among the various priority categories.

Standard 9 - Program Assessment; Essential Service # 5 – Develop policies and Plans

This standard applies to the process used to measure the success of jurisdictions in meeting the *Voluntary National Retail Food Regulatory Program Standards 1 through 9* (hereafter referred to as the National Standards) and their progress in reducing the occurrence of foodborne illness risk factors. Additionally, it applies to the requirements for recognition by the Food and Drug Administration of those jurisdictions meeting the National Standards.

Requirement Summary

1. For listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure:

A. That the program manager conducts an initial *self-assessment* within 12 months of the date of enrollment in the National Registry and every 36 months thereafter; and,
B. That a *verification audit* is conducted within 36 months of the initial *self-assessment*. Subsequent verification audits are conducted every 36 months thereafter.

2. For achievement of Standard 9, a jurisdiction must assure:
   A. That a survey and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit; and
   B. A survey on the occurrence of risk factors and *Food Code* interventions is conducted at least once every five years thereafter to measure trends specific to the occurrence of the risk factors and interventions.
3. Reporting by means of the FDA National Registry Report form.

Description of Requirement

For Listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure that:

1. **Self-Assessment:**
   The program manager, or a designated representative, conducts an initial *self-assessment* of the retail food safety program within 12 months of the date of enrollment in the National Registry and every 36 months thereafter. The *self-assessment* will determine:
   A. The compliance status with each of the National Standards by completing the Appendix documents (hereafter referred to as the worksheets) or documents containing equivalent summary information for each Standard, and
   B. Whether the *quality records* specified as requirements in each of the National Standards have been established, identified, and maintained. If the quality records for a specific program element are incomplete or provide inadequate information upon which to make a determination or to enable a verification audit, that standard is not met.
2. **Verification Audit:**
   The first *verification audit* is conducted within 36 months the initial self-assessment. An individual as defined in the definitions shall complete the verification audit. Subsequent verification audits are conducted every 36 months thereafter. Verification audits confirm and report on the accuracy of the *self-assessment* and the occurrence of risk factors and *Food Code* interventions survey reports. During the *verification audit*, the auditor will:
   A. A. Review the *quality records* and confirm that the *self-assessment* accurately reflects the current program compliance status in each of the program elements, and
   B. B. Confirm that the occurrence of risk factors survey collection procedures and survey tools similar to Appendix J have been used and that the conclusions are supported by the data.
3. **Achievement of Standard 9,**
   A jurisdiction must assure that a baseline survey and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit. The survey information is updated at least once in every 5 years to measure trends specific to the occurrence of the risk factors and *Food Code* interventions. The subsequent surveys and

reports will determine whether there has been a net change in the occurrence of the risk factors and use *Food Code* interventions.

A data collection instrument similar to the FDA model form referenced in 2.B., using the IN, OUT, NA, and NO convention, is required. Failure to use this convention skews the data toward either IN compliance or OUT of compliance. The FDA data collection instrument is not intended as an inspection form. However, jurisdictions that have developed an inspection form using the IN, OUT, NA and NO convention may use that inspection form as a survey instrument. Refer to the Data Collection Manual to understand the statistical limitations and restrictions if using an inspection form or a data collection form different from the FDA data collection instrument. If the jurisdiction uses a different form, the data may be difficult to compare with the data from the FDA national foodborne illness risk factor study or with data from other jurisdictions.

4. **Reporting:**
   The FDA National Registry Report (Standards Appendix I) will be completed and submitted to the appropriate FDA Regional office within 30 days following completion of the self-assessment, survey report on the occurrence of foodborne illness risk factors and *Food Code* interventions, verification audits, and/or survey of risk factor occurrence updates. The FDA National Registry listing will be updated using data contained in this report. A current Release and Permission to Publish Form must accompany each FDA National Registry Report.

Outcome

The desired outcome of this Standard is to enable managers to measure their program against national criteria. The process identifies program elements that may require improvement or be deserving of recognition.

Documentation

The quality records required for this standard include:

1. The completed Appendices (worksheets) for each Standard and supporting records,
2. Survey reports on the occurrence of risk factors and *Food Code* interventions,
3. Verification audit report,
4. FDA National Registry Report, and
5. Affidavit of Permission to Publish.